IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JOSE LUIS GONZALEZ DIAZ, individually and on behalf of all others similarly situated and derivatively on behalf of ACER THERAPEUTICS INC., Plaintiff, v. JASON AMELLO, STEVE ASELAGE, HUBERT BIRNER, JOHN M. DUNN, MICHELLE GRIFFIN, LUC MARENGERE, HARRY PALMIN, and CHRIS SCHELLING, Defendants, - and - ACER THERAPEUTICS INC., Nominal Defendant.	C.A. No. _____-_____

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff Jose Luis Gonzalez Diaz ("Plaintiff"), by and through his undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Acer Therapeutics Inc. ("Acer" or the "Company"), against Individual Defendants Jason Amello ("Amello"), Steve Aselage ("Aselage"), Hubert Birner ("Birner"), John M. Dunn ("Dunn"), Michelle Griffin ("Griffin"), Luc Marengere ("Marengere"), Harry Palmin ("Palmin"), and Chris Schelling ("Schelling") (collectively, the "Individual Defendants," and together with Acer, the "Defendants") for breaches of fiduciary duties, unjust enrichment, waste of

corporate assets, and violations of the Securities Exchange Act of 1934 (the "Exchange Act").

Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Acer with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action that seeks to remedy wrongdoing committed by Acer's current and/or former directors and officers from September 25, 2017 through the present (the "Relevant Period").

2. Acer was founded as a private company in 2013 and is headquartered in Newton, Massachusetts. A pharmaceutical company, Acer develops and commercializes medications aimed at treating rare and life-threatening diseases. One of the Company's medications is EDSIVO (celiprolol). EDSIVO is a medication intended for the treatment of vascular Ehlers-Danlos Syndrome ("vEDS"), a rare genetic disease known to cause abnormal fragility in blood vessels, causing aneurysms, abnormal connections between blood vessels known as

arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which are potentially life-threatening.

3. Since the Company's founding in 2013, the Company has poured much of its resources into EDSIVO, including funding research and purchasing clinical studies into the efficacy of celiprolol in the hopes of obtaining U.S. Food and Drug Administration ("FDA") approval for the drug—a prerequisite for new drugs to be marketed and sold in the U.S.

4. To date, none of the Company's drug candidates have received FDA approval, meaning the Company is yet to generate any revenue.

5. Having incurred losses every year since its founding, under the Individual Defendants' direction, Acer conducted two secondary public offerings in order to raise funds, one in December 2017 and the other in August 2018 (respectively, the "December 2017 Offering" and the "August 2018 Offering').

6. In prospectus supplements issued in connection with these public offerings, as well as other public filings issued throughout the Relevant Period, the Individual Defendants: (a) touted EDSIVO's future prospects; (b) represented that the Company was collaborating with the FDA; and (c) represented that the new drug application ("NDA") for EDSIVO would be approved.

7. To support their representations, the Individual Defendants directed the public to, among other things, data gathered through a French clinical trial published

in October 2010 involving the use of celiprolol (the "Ong Trial") as well as data gathered from a long-term study of vEDS patients published by the *Journal of the American College of Cardiology* in April 2019 (the "Long Term Observational Study"). Such data purportedly indicated that celiprolol was effective as a treatment for symptoms of vEDS, which therefore supported EDSIVO's approval for use in the U.S.

8. Unfortunately, and to the detriment of both the Company and its stockholders, both studies were limited to such an extent that they did not provide an adequate basis to support FDA approval of EDSIVO. The Ong Trial was fundamentally flawed, lacked a sufficient sample size, and was severely biased. The Long-Term Observational Study lacked a control group—making it nigh impossible to assess what, if any, effect celiprolol had on the survivability of the vEDS patients who were monitored in the study.

9. Due to the Company's financial struggles, the Individual Defendants failed to disclose any of the flaws described above to stockholders. Indeed, the Individual Defendants misleadingly emphasized that the FDA had agreed that an additional clinical trial beyond the Ong Trial "is not needed" or "is not likely needed," indicating that the EDSIVO NDA would more than likely be approved. In reality, Acer and the FDA had not reached an agreement that the Company would not need to conduct additional clinical studies beyond the already-completed Ong

Trial. In sum, the Individual Defendants repeatedly misrepresented the Company's communications with the FDA regarding EDSIVO.

10. Indeed, throughout the Relevant Period, the Individual Defendants made a series of materially false and misleading statements regarding the Company's business, operational, and compliance policies. Specifically, the Individual Defendants made false and/or misleading statements and/or failed to disclose that: (a) Acer lacked sufficient data to support filing EDSIVO's NDA with the FDA for the treatment of vEDS; (b) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO's NDA; and (c) consequently, the FDA would likely reject EDSIVO's NDA.

11. The truth emerged on June 25, 2019. On that date, the Individual Defendants caused Acer to issue a press release titled "Acer Therapeutics Receives Complete Response Letter from U.S. FDA for use of EDSIVO™ (celiprolol) in vEDS Patients" (the "June 2019 Press Release").[1] In the June 2019 Press Release, Acer disclosed that the FDA had denied the Company's EDSIVO NDA and that "[t]he CRL states that it will be necessary to conduct an adequate and well-controlled

[1] "Complete Response Letter" or "CRL" is a term of art found in 21 C.F.R. 314.110, which essentially states that the FDA has completed its review of a new or generic drug application, and it decided that it will not approve it for marketing in its present form.

trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS."

12. The Individual Defendants admitted the Company would be required to now "conduct an adequate and well-controlled trial" beyond the insufficient Ong Trial. That same day, news sources reported that the small group size of the Ong Trial had raised questions among experts about the adequacy of EDSIVO's trial results.

13. Following this news, Acer's stock price fell by $15.16 per share, or ***nearly 79%***, to close at $4.12 per share on June 25, 2019. The Company's stock price has not recovered, and currently trades for less than $3.25 per share.

14. On July 5, 2019, the Individual Defendants disclosed that the Company would be implementing a "corporate restructuring" as a result of EDSIVO's rejection by the FDA, which included downsizing employees and halting pre-commercial activities related to EDSIVO.

15. The Individual Defendants failed to correct and/or caused the Company to fail to correct false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties. In further breach of their fiduciary duties, the Individual Defendants willfully or recklessly caused the Company to fail to maintain an adequate system of oversight, disclosure control and procedures, and internal controls over financial reporting.

16. Following the disclosure of the events described herein, Acer investors filed a class action lawsuit in the U.S. District Court for the Southern District of New York against the Company and defendants Schelling and Palmin for violations of the Securities Exchange Act of 1934. *See Skiadas v. Acer Therapeutics, et al.*, Case No. 19-cv-06137-GHW (S.D.N.Y.) (the "Securities Class Action"). The Securities Class Action is brought on behalf of a "class" consisting of all persons or entities who purchased or acquired Acer stock between December 12, 2017 and June 24, 2019 (the "Class Period"). The operative complaint in the Securities Class Action was filed on February 28, 2020.

17. The Company has incurred substantial costs resulting from the (thus far) unsuccessful defense of the Securities Class Action, the costs associated with internal investigations, losses from the waste of corporate assets, and losses due to the unjust enrichment of Individual Defendants who were improperly over-compensated by the Company. These events have already cost Acer millions of dollars and will likely cost the Company millions more in the future.

18. On June 16, 2020, District Judge Gregory H. Woods denied in substantial part the defendants' motion to dismiss the Securities Class Action, finding that it had been adequately alleged that a series of statements issued by Acer, defendant Schelling, the Company's President and Chief Executive Officer ("CEO"), and defendant Palmin, which represented that the FDA had "agreed" that

no additional clinical trials for EDSIVO were necessary for EDSIVO to receive FDA approval, were materially false and misleading. Securities Class Action Order at 15–17, *Skiadas v. Acer Therapeutics Inc., et al.*, Docket No. 1:19-cv-06137-GHW, (S.D.N.Y. June 16, 2020) ("Securities Class Action Order").

19. Judge Woods further concluded that it had been plausibly alleged that the defendants to the Securities Class Action acted with scienter. In other words, Judge Woods found there was *indicia* that the defendants participated in a scheme to defraud Acer investors during the Class Period.

20. In light of the Individual Defendants' (most of whom are the Company's current directors) non-exculpable breaches of fiduciary duty, the collective engagement in misconduct by the Company's current directors, the substantial likelihood of the CEO's liability in the Securities Class Action, and the current directors' liability in this derivative action, and their not being disinterested or independent directors, a majority of the Board cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

JURISDICTION AND VENUE

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under §§14(a), 10(b), and 21D of the Exchange Act, 15 U.S.C. § 78n and Rule 14a-9 of the Exchange Act, 17 C.F.R.

§ 240.14a-9.

22. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

23. This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

24. This Court has personal jurisdiction over the Company because it is incorporated in this District, and each of the Individual Defendants has minimum contacts with this District to justify the exercise of jurisdiction over them.

25. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

26. Venue is proper in this District because Acer is incorporated in Delaware, the Defendants have conducted business in this District, and Defendants' actions have had an effect in this District.

PARTIES

Plaintiff

27. Plaintiff Jose Luis Gonzalez Diaz is a current stockholder of Acer common stock. Plaintiff has held Acer common stock since September 2010 and has continuously held at all relevant times.

Nominal Defendant

28. Nominal Defendant Acer is a Delaware corporation, with its principal executive offices located at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts. Acer's securities trade on NASDAQ under the symbol "ACER."

Individual Defendants

29. Defendant Amello has served as a director of Acer since September 2017. He also serves as a member of the Company's Audit Committee.

30. Defendant Aselage has served as a director of Acer since September 2017. He also serves as the Chair of the Company's Compensation Committee, and as a member of the Nominating and Corporate Governance Committee.

31. Defendant Birner served as a Company director from September 2017 until he resigned on May 17, 2019.

32. Defendant Dunn has served as a director of Acer since September 2017. He also serves as the Chair of the Company's Nominating and Corporate Governance Committee, and as a member of the Audit Committee.

33. Defendant Griffin has served as a director of Acer since September 2017. Griffin also serves as the Chair of the Company's Audit Committee, and as a member of the Compensation Committee.

34. Defendant Marengere served as a Company director from September

2017 until he resigned on May 17, 2019.

35. Defendant Palmin has served as Acer's CFO since September 2017. Palmin has also served as Acer's Chief Operating Officer ("COO") since September 1, 2018. Previously, Palmin served as the Company's President and CEO from December 2013 through February 2016.

36. Defendant Schelling has served as Acer's President and CEO since September 2017. Schelling has also served as a director of Acer since September 2017.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

37. Each Individual Defendant, by virtue of his/her position as a director and/or officer, owed to Acer and to its stockholders the fiduciary duties of loyalty and care. The Individual Defendants were, and are, required to act in furtherance of the best interests of Acer and its stockholders so as to benefit all stockholders equally and not in furtherance of their personal interests or benefit.

38. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Acer, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Acer, each Individual Defendant had knowledge of material non-public information regarding the Company.

39. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information.

40. To discharge their duties, the officers and directors of Acer were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the Company. By virtue of such duties, the officers and directors of Acer were required to, among other things:

a. Ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations, and requirements, and all contractual obligations, including acting only within the scope of its legal authority, and pursuant to Acer's Policy on Whistleblower Protections and Code of

Ethics (the "Code of Ethics");

b. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

c. Exercise good faith to ensure that the Company's communications with the public and with stockholders are made with due candor in a timely and complete fashion; and

d. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

ACER'S CODE OF ETHICS

41. The Company's Code of Ethics states that it "reiterates the standards of conduct and ethical behavior that we have always expected of our directors, officers and employees (collectively, "Representatives" and individually, a "Representative")."

42. The Code of Ethics further provides that it was designed to promote the following:

a. honest and ethical conduct, including the ethical handling of actual and apparent conflicts of interest between personal and professional relationships;

b. full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the SEC and in other public communications made by the Company;

c. compliance with applicable governmental laws, rules and regulations;

d. the prompt internal reporting to an appropriate person or persons identified in the Code of violations of the Code; and

e. accountability for adherence to the Code.

43. In "Honest and Candid Conduct," the Code of Ethics states the following:

> Representatives are expected to act and perform their duties ethically and honestly with the utmost integrity. Honest conduct is considered to be conduct that is free from fraud or deception. Ethical conduct is considered to be conduct conforming to accepted professional standards of conduct. Ethical conduct includes the ethical handling of actual or apparent conflicts of interest between personal and professional relationships as discussed below.

44. In "Accuracy of Financial Reports and Other Public Communications," the Code of Ethics states the following:

> The Company, as a public company, is subject to various securities laws, regulations and reporting obligations. Both federal law and our policies require the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations which may be filed with, or submitted to, the SEC and other regulators or disseminated publicly. Inaccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability.

> Senior Financial Officers are responsible for ensuring that the disclosure in the Company's periodic reports is full, fair, accurate, timely and understandable. In doing so, Senior Financial Officers shall take such action as is reasonably appropriate to (i) establish and comply with disclosure controls and procedures and accounting and financial controls that are designed to ensure that material information relating to the Company is made known to them, (ii) confirm that the Company's periodic reports comply with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and (iii) ensure that information contained in the Company's periodic reports fairly presents in all material respects the financial condition and results of operations of the Company.

45. In "Compliance with Laws and Regulations," the Code of Ethics states the following:

> It is the Company's policy to comply with all applicable laws, rules, and regulations. It is the personal responsibility of each Representative to adhere to the standards and restrictions imposed by those laws, rules, and regulations. In performing his or her duties, each Representative will endeavor to comply, and take appropriate action within his or her areas of responsibility to cause the Company to comply, with applicable governmental laws, rules, and regulations.

46. In "Monitoring Compliance and Disciplinary Action," the Code of Ethics states the following:

> The Company's management, under the supervision of its Board of Directors or a committee thereof, or, in the case of accounting, internal accounting controls or auditing matters, the Audit Committee, shall take reasonable steps from time to time to (i) monitor compliance with the Code, including the establishment of monitoring systems that are reasonably designed to investigate and detect conduct in violation of the Code, and (ii) when appropriate, impose and enforce appropriate disciplinary measures for violations of the Code.

47. In violation of the Code of Ethics, the Individual Defendants issued a

series of materially false and misleading statements to the public and facilitated and disguised their violations of law, including breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the Exchange Act. Also in violation of the Code of Ethics, the Individual Defendants failed to maintain the accuracy of Company records and reports, failed to comply with laws and regulations, failed to conduct business in an honest and ethical manner, and failed to properly report violations of the Code of Ethics.

AUDIT COMMITTEE DUTIES

48. The Board's Audit Committee Charter lists specific duties and responsibilities for members of the Audit Committee. For example, Audit Committee members are tasked with "assist[ing] the Board in its oversight of: (1) the integrity of the Company's financial statements, financial reporting process, and systems of internal controls relating to finance, accounting, legal and regulatory compliance." In addition, the Audit Committee members are required to "discuss with the Company's general counsel (or person or entity performing such function) any significant legal, compliance or regulatory matters that may have a material effect on the financial statements or the Company's business, financial statements or compliance policies, including material notices to or inquiries received from governmental agencies."

SUBSTANTIVE ALLEGATIONS

Company Overview and Background

49. Acer is a pharmaceutical company, founded in 2013 and headquartered in Newton, Massachusetts, that focuses on the acquisition, development, and commercialization of therapies for rare and life-threatening diseases. Acer's pipeline includes, *inter alia*, EDSIVO (celiprolol) for the treatment of vEDS in patients with a confirmed type III collagen mutation.

50. vEDS is a rare disease known to cause abnormal fragility in blood vessels, causing aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which are potentially life-threatening.

51. EDSIVO is the brand name the Company has assigned to its celiprolol candidate. While celiprolol is currently used in the European Union (and has been for over 30 years) as a treatment for hypertension and vEDS, the drug has not received FDA approval. Until it does receive such approval, its sale is prohibited in the United States.

52. To date, none of the Company's drug candidates have received FDA approval, meaning the Company has yet to generate any revenue. Analysts reporting on Acer have estimated that if EDSIVO receives FDA approval, the Company could

charge vEDS patients as much as $100,000 per year for the drug.

The Ong Trial and Long-Term Observational Study

53. In 2004, a French research hospital, Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP"), published data on vEDS patients. Based on AP-HP's research, investigators began assessing the preventive effect of celiprolol for major cardiovascular events in patients suffering from vEDS "through a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events"—the Ong Trial.

54. On December 13, 2016, Acer issued a press release announcing that it had obtained exclusive rights to NDA-enabling clinical data from AP-HP for the use of celiprolol in treating vEDS. Specifically, Acer had signed an agreement with AP-HP, which granted exclusive rights to access and use data from the Ong Trial. Private Acer announced it would use this data to support its NDA for celiprolol in the treatment of vEDS.

55. The Ong Trial was a multicenter, randomized clinical trial based on data gathered by AP-HP researchers in 2004 from vEDS patients. The objective of the Ong Trial was to determine the efficacy of celipolol as a means of lowering the risks of arterial dissection and vascular rupture in vEDS patients.

56. According to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "2019 10-K"), the Ong Trial was described

as follows:

> Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patient ages ranged from 15 to 65 (with a mean age of 35), with a female-to-male ratio of 2-to-1. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, with important phenotype characteristics equally balanced between the celiprolol group and the control group. Celiprolol was administered twice daily to patients in the celiprolol group and the dosage was up-titrated every six months by 100 milligrams per day to a maximum of 400 milligrams per day. Patients assigned to the control group received the same attention as those assigned to the celiprolol group but did not receive celiprolol or any beta blocker. Thirty-three of the 53 patients participating in the study had proven mutations in the COL3A1 gene. Of those patients with proven mutations, demographic and arterial characteristics did not differ from those of the study population as a whole. The duration of follow-up was five years or until the first qualifying cardiac or arterial event. The primary endpoint was a composite of cardiac or arterial events (rupture or dissection, fatal or not) during follow-up. Secondary endpoints were gastrointestinal or uterine rupture. The study was ended early after a consensus decision of the safety monitoring board, the methodologist of AP-HP, and the principal investigator because significant differences were recorded between the treatment group and the control group after 64 months.

57. The 2019 10-K failed to disclose, however, that the Ong Trial was severely limited and flawed. For example, there was a substantial imbalance between the treatment group and the control group of patients in the Ong Trial—specifically, 12 out of the 25 patients in the treatment group did not possess the COL3A1 gene mutation (and 13 who did), which is the cause of vEDS. In contrast, the control group consisted of 8 patients who did not have the COL3A1 mutation, and 20 who did. This created a severe imbalance between the treatment group and the control group.

58. Due to this imbalance, the treatment group had a roughly 19% head start towards event-free survival, which is highly material and equates to a 5-event advantage for the treatment group (an event being a vascular rupture or arterial dissection) over the control group (*i.e.*, progressing through the trial without suffering any rupture or dissection). In light of the fact that an 8-event advantage in a clinical trial is generally considered to be statistically significant, any outcome in the Ong Trial in which there are at least three fewer events among the 13 patients with the mutation in the treatment group than among the 20 patients with the mutation in the control group would result in a statistically significant survival advantage for the treatment group. For this reason, the Ong Trial was biased from the start in favor of indicating that celiprolol could increase patients' rate of survival.

59. Furthermore, only 33 patients (13 + 20) in the Ong Trial possessed the COL3A1 mutation—an inadequate sample size to test for meaningful differences between the treatment group and the control group.

60. The Ong Trial was also a retrospective study, as it was based on an analysis of historical data. This is significant because the FDA has demonstrated preference for prospective, rather than retrospective studies. The FDA likely would have viewed the retrospective nature of the Ong Trial as an additional source of bias.

61. These red flags indicating the fallibility of the Ong Trial are corroborated by an independent expert cited to in the operative complaint in the

Securities Class Action, who opined, among other things, that each of the above-described flaws in the Ong Trial were red flags that the FDA would have immediately recognized upon reviewing the trial data.

62. On January 28, 2019, an article published by Pharmaceutical Technology commented on the various insufficiencies of the Ong Trial:[2]

> Acer Therapeutics' Edsivo (celiprolol) is not expected to win approval from the US Food and Drug Administration (FDA) for vascular Ehlers-Danlos syndrome (vEDS), as the registrational trial was too small and not well-controlled, according to experts.
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> Other experts interviewed said that given the trial comprised of 53 patients, the Phase IV trial (NCT00190411) was too small even for a rare disease like vEDS.
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> The study that the approval of Edsivo would be based on was not well-designed, with an overall small trial size, said vEDS expert Dr Harry Dietz, Co-director of the Medical Genetics Fellowship Training Programme and Professor of Paediatrics at The Johns Hopkins Hospital, Baltimore, Maryland, US.
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> Besides the low patient figures, the imbalance between the experimental and control arms in terms of patients with the COL3A1 mutation means the results are also insufficient for FDA approval, said Dr Dietz and Dr Grossfeld.

63. Six months later, the Marfan Foundation similarly questioned the reliability of the Ong Trial when it published an article on June 25, 2019 stating the

[2] https://www.pharmaceutical-technology.com/comment/ehlers-danlos-syndrome-treatment/ (last visited June 26, 2020).

following:[3]

> The Marfan Foundation, as well as representatives of its Professional Advisory Board, have reviewed the underlying studies of the drug and agree that celiprolol does not warrant designation as a sole approved drug for the treatment of people with vEDS (see background below). The Foundation recommends that registries of affected individuals with *COL3A1* mutations be assembled quickly to facilitate informative clinical trials.
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> The consensus expressed at the international vascular Ehlers-Danlos syndrome meeting in Amsterdam in May 2018 emphasized the need for a large and well-controlled clinical trial of celiprolol in vEDS and the eagerness of the international medical community to assist in this effort.

64. Despite having knowledge of the severe bias issues in the Ong Trial, which significantly lowered the chance of FDA approval for EDSIVO, the Individual Defendants touted the purported positive results of the Ong Trial while omitting its flaws.

65. The Individual Defendants also touted data from the Long-Term Observational Study, a study published in April 2019 in the *Journal of the American College of Cardiology* consisting of data gathered from COL3A1-positive vEDS patients between 2000 and 2017. In a press release issued by the Company on April 16, 2019, the Individual Defendants quoted one of the authors of the study as stating, "The higher overall survival in patients treated with celiprolol in this long-term study

[3] https://www.marfan.org/about-us/news/2019/06/25/marfan-foundation-statement-celiprolol#.XvEiRmhKiUk (last visited June 26, 2020).

in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the [Ong Trial] of celiprolol treatment in vEDS patients."

66. This selective quotation provided by the Individual Defendants lacked the proper framework. Indeed, the researchers of the Long-Term Observational Study noted that it was difficult to assess whether celiprolol actually increased the survivability of patients monitored in the study, as the study lacked a placebo-control, and therefore "other confounders" might have influenced the study's outcome.

67. Dr. Julie De Backer and Dr. Tine De Backer, vEDS researchers who were not involved in the Long-Term Observational Study, commented on the study as follows:

> ***Whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial effect or helps ensure better follow up cannot be answered with this study.*** The only way to determine if it is celiprolol contributing to the better outcome is to conduct a randomized prospective trial comparing celiprolol to another beta-blocker in patients with molecularly confirmed vEDS.

(Emphasis added.)

68. Despite the critical flaws described above, throughout the Relevant Period, the Individual Defendants repeatedly showcased the supposedly positive results of the Ong Trial and the Long-Term Observational Study to indicate to the public that the FDA was likely to approve EDSIVO, and had even "agreed" that

further clinical trials would not be necessary.

The FDA Approval Process

69. All prospective new drugs in the United States, like EDSIVO, must receive FDA approval before they can be marketed and sold to the public.

70. The FDA approves a new drug for sale and marketing in the United States through an NDA process. As stated on the FDA's website, "[t]he goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity."[4]

71. Further, the FDA describes that the NDA "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body,

[4] https://www.fda.gov/drugs/types-applications/new-drug-application-nda#:~:text=The%20goals%20of%20the%20NDA,the%20drug%20outweigh%20the%20risks. (last visited June 26, 2020)

and how it is manufactured, processed and packaged."[5]

72. From September 2017 onward, the Individual Defendants repeatedly signaled to the public that FDA approval of EDSIVO was all but inevitable. The Individual Defendants represented that the FDA was working closely with Acer to prepare the EDSIVO NDA, and that the FDA had agreed during a September 2015 meeting that "additional clinical development is not needed." Later in the Relevant Period, the Individual Defendants would belatedly revise this description of the FDA's so-called "agreement," stating more specifically that the FDA has "agreed that an additional clinical trial is not ***likely*** needed." (Emphasis added).

73. The Individual Defendants also caused the Company to make a number of senior-level hires throughout the Relevant Period, including adding various new Vice Presidents to the Company's marketing and medical affairs departments, "[a]s part of the pre-commercial preparation" for EDSIVO.

74. However, the FDA could not have considered the Ong Trial as adequate support for approval of EDSIVO. Indeed, the Individual Defendants knew or should have known that the FDA was not likely to approve EDSIVO's NDA.

The Individual Defendants' False and Misleading Statements

September 25, 2017 Press Release

75. The Relevant Period begins on September 25, 2017, when the

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5 *Id.*

Individual Defendants caused Acer to issue a press release announcing "Positive Results From Pivotal Clinical Trial of EDSIVO" for the treatment of vEDS (the "September 2017 Press Release"). Despite the Ong Trial's small group size of only fifty-three participants, the September 2017 Press Release touted the Ong Trial as a comprehensive study with positive results that would support Acer's NDA for EDSIVO, stating, in relevant part:

> [Acer] today announced positive results from the pivotal clinical trial of EDVISO (celiprolol) for the treatment of [vEDS]. Acer's retrospective source verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol(1). Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.
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> The previously completed European study, published on October 30, 2010, in *The Lancet*, was stopped early having achieved statistical significance in its primary endpoints . . . .

76. The September 2017 Press Release also included a statement by Pierre Boutouyrie ("Boutouyrie") M.D., Ph.D., co-director of the clinical pharmacology service at AP-HP, and Principal Investigator for the published celiprolol study. Boutouyrie touted "nearly two decades" worth of data obtained on EDSIVO in vEDS patients and that the drug was the "standard of care" for vEDS patients in France. Specifically, Boutouyrie stated:

> We have studied celiprolol for nearly two decades in vEDS patients and this is the only drug to ever demonstrate a clinical benefit in this

> difficult to treat patient population in a randomized, controlled clinical study . . . . Having established celiprolol as the standard of care in France for vEDS patients, we are excited to collaborate with Acer to help bring celiprolol to U.S. patients who are suffering from this devastating, life-threatening disease.

77. Additionally, the September 2017 Press Release included a statement by Acer's Chief Medical Officer, Robert D. Steiner, M.D., who stressed that the Company had vetted the Ong Trial data, and that this data was a "critical element" of EDSIVO's NDA:

> Our confirmation of the published celiprolol clinical data with an Acer-sponsored retrospective source verified analysis of the trial data represents a critical element of the clinical module in our NDA, which we are diligently building, along with current manufacturing, non-clinical and other components of the regulatory package.

78. Finally, the September 2017 Press Release included a statement by Defendant Schelling, who touted the Ong Trial as a "robust" clinical study with endpoints verified by Acer, which would "rapidly advance" EDSIVO's product development:

> We continue to successfully rapidly advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS, towards an NDA filing, which we expect to accomplish in the first half of 2018 . . . . In addition to source verifying a definitive Event-Free Survival endpoint from a previously completed robust clinical study, modernizing manufacturing and assembling other components of the regulatory package, we are executing on a number of key medical affairs focused initiatives for vEDS patients. Specifically, we are setting up Centers of Excellence to optimize patient care, and intend to develop a prospective vEDS Patient Registry and provide integrated care support programs.

November 13, 2017 Press Release

79. On November 13, 2017, the Individual Defendants caused the Company to issue a press release containing the Company's financial results for the fiscal quarter ended September 30, 2017. The press release quoted Defendant Schelling, who commented on the development of EDSIVO as follows:

> "The third quarter was transformative for Acer. We became a public Nasdaq-listed company, closed a concurrent financing ***and announced positive results from our pivotal clinical trial of EDSIVO™, each a critical step in bringing us closer to our goal of becoming a leading pharmaceutical company that acquires, develops and commercializes therapies for the treatment of patients with serious rare and ultra-rare diseases with critical unmet medical need,"*** said Chris Schelling, CEO and Founder of Acer. ***"We continue to successfully advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS***. We believe that our current cash position will allow us to advance EDSIVO™ through NDA submission with the FDA in the first half of 2018. As a public company, we look forward to advancing and expanding our pipeline with the goal of bringing multiple products to patients over the next several years."
> (Emphasis added.)

November 13, 2017 Form 10-Q

80. On November 13, 2017, the Individual Defendants also caused the Company to file its quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2017 with the SEC (the "November 2017 10-Q"). The November 2017 10-Q was signed by defendant Palmin, and contained certifications pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") signed by defendants Schelling and Palmin attesting to the

accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

81. The November 2017 10-Q stated the following regarding the Company's internal controls:

> We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms, and that information is accumulated and communicated to our management, including our principal executive officer and principal financial officer (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of September 30, 2017, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of September 30, 2017, our disclosure controls and procedures were effective.
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> * * *
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> There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

December 2017 Offering Documents

82. On December 11, 2017, the Individual Defendants caused the Company to file a preliminary prospectus supplement on Form 424B3 with the SEC in connection with the Company's planned December 2017 Offering (the "December

11, 2017 Form 424B3"). Subsequently, on December 12, 2017, the Individual Defendants caused the Company to file an additional preliminary prospectus supplement on Form 424B3 with the SEC (the "December 12, 2017 Form 424B3," and together with the December 11, 2017 Form 424B3, the "December 2017 Offering Documents"). The December 2017 Offering Documents described the Company's purported meeting with the FDA concerning EDSIVO, stating the following:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS***. In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional ten-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS in the first half of 2018.

(Emphasis added.)

83. In connection with the December 2017 Offering, the Company sold over one million shares of stock and raised approximately $12.5 million.

March 7, 2018 Press Release

84. On March 7, 2018, the Individual Defendants caused the Company to issue a press release containing the Company's financial results for the fiscal quarter and full year ended December 31, 2017. The press release included a section on "2017 and Recent Highlights," which discussed purported positive results from the Company's EDSIVO trials as follows:

> Announced positive results from the pivotal clinical trial of EDSIVO™ (celiprolol) for the treatment of vEDS. Our retrospective source-verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol(1). We plan to discuss these key data during a pre-NDA meeting with the FDA in the second quarter of 2018.

March 7, 2018 Form 10-K

85. On March 7, 2018, the Individual Defendants also caused Acer to file an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fiscal year ended December 31, 2017 (the "2017 10-K"). The 2017 10-K was signed by all of the Individual Defendants, and contained SOX certifications signed by defendants Schelling and Palmin attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

86. Under the 2017 10-K's "Rationale for EDSIVO™ Treatment in vEDS" section heading, the Individual Defendants heavily relied upon the methodology and results of the Ong Trial. Additionally, under the 2017 10-K's "Registration Plan" section heading for EDSIVO, the Individual Defendants touted their meeting with the FDA and indicated that the FDA had sanctioned the Ong Trial as a sufficient source of data to support the EDSIVO NDA, stating, in relevant part:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS.*** The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.

(Emphasis added.)

87. Additionally, according to the Individual Defendants' representations in the 2017 10-K, Acer had consulted with the FDA regarding potential data gaps that could hinder the Company's EDSIVO NDA filing. According to the 2017 10-K, the Individual Defendants had received additional guidance concerning these gaps. Specifically, the 2017 10-K stated, in relevant part:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there

> were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.
>
> We plan to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018. Subsequently, we expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS at the end of the first half of 2018.

88. The 2017 10-K also contained generic, boilerplate representations from the Individual Defendants concerning the risk that regulatory approval for EDSIVO might prove more expensive and time-consuming than initially anticipated. For example, the 2017 10-K stated, in relevant part:

> ***Our product candidate EDSIVO™ has not been approved for any indication in the United States, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.***
>
> EDSIVO™ is a repurposing of celiprolol for the treatment of vEDS. An NDA for this drug in the treatment of hypertension was submitted to the FDA in 1987, however, the NDA was withdrawn prior to review. However, the drug has been approved in Europe for the treatment of hypertension since 1984. Regulatory approval of EDSIVO™ may be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical product candidates due to our and regulatory agencies' lack of experience with celiprolol. The novelty of this product candidate may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our

> product candidates or lead to significant post-approval limitations or restrictions. There is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our clinical trials and beyond. Any such events could adversely impact our business prospects, financial condition and results of operations.

(Emphasis in original.)

89. Additionally, the 2017 10-K contained generic, boilerplate representations from the Individual Defendants concerning the risk that Acer's stock price could suffer dramatic changes due to, *inter alia*, "the development status of any of [Acer's] drug candidates, such as EDSIVO™[.]"

April 9, 2018 Proxy Statement

90. On April 9, 2018, the Individual Defendants caused the Company to file a Schedule 14A with the SEC (the "2018 Proxy Statement"). Defendants Schelling, Amello, Aselage, Birner, Dunn, Griffin, and Marengere each signed the 2018 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.

91. The 2018 Proxy Statement was false and misleading because, despite noting that the Company maintains procedures regarding "corporate governance and ethical conduct," such procedures, including the Code of Ethics, were not followed, as evidenced by the numerous false and misleading statements alleged within this Complaint, and the Individual Defendants' failures to report violations of the Code of Ethics.

92. The 2018 Proxy Statement failed to disclose, among other things, that: (a) the Ong Trial was substantially biased and underpowered, and would be inadequate to support FDA approval of EDSIVO; (b) the FDA had not "agreed" that further clinical trials for EDSIVO were not needed for the approval of EDSIVO's NDA; (c) due to the foregoing, it was highly unlikely that EDSIVO's NDA would ultimately be approved; and (d) the Company failed to maintain an adequate system of internal controls.

93. The 2018 Proxy Statement also called for stockholder approval of, among other things, the Acer 2018 Stock Incentive Plan (the "2018 Stock Incentive Plan"), which would authorize the Company to reserve 500,000 shares of Company stock, in addition to shares of Company stock subject to outstanding awards under prior stock incentive plans, to be issued to the Company's officers and directors in connection with performance-based awards.

94. As a result of the Individual Defendants' material misstatements and omissions contained in the 2018 Proxy Statement, Company stockholders approved the 2018 Stock Incentive Plan.

May 14, 2018 Form 10-Q

95. On May 14, 2018 the Individual Defendants caused the Company to file its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018 with the SEC (the "May 2018 10-Q"). The May 2018 10-Q was signed by defendant

Palmin, and contained SOX certifications signed by defendants Schelling and Palmin attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

96. Regarding the Company's internal controls, the May 2018 10-Q stated the following:

> We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the SEC under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the SEC's rules and forms, and that information is accumulated and communicated to our management, including our principal executive officer and principal financial officer (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of March 31, 2018, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of March 31, 2018, our disclosure controls and procedures were effective.
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> * * *
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> There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

August 2018 Offering Documents

97. On July 31, 2018, the Individual Defendants caused the Company to file a preliminary prospectus supplement on Form 424B3 with the SEC in connection with the Company's planned August 2018 Offering (the "July 31, 2018 Form

424B3"). Subsequently, on August 1, 2018, the Individual Defendants caused the Company to file a preliminary prospectus supplement on Form 424B2 with the SEC (the "August 1, 2018 Form 424B2," and together with the July 31, 2018 Form 424B3, the "August 2018 Offering Documents").

98. Like the December 2017 Offering Documents and the 2017 10-K, the August 2018 Offering Documents described the Company's meeting with the FDA concerning EDSIVO as follows:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS.*** In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional 10-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS in the first half of 2018.

(Emphasis added.)

99. In connection with the August 2018 Offering, the Company sold over 2.5 million shares of stock and raised approximately $46 million.

August 13, 2018 Form 10-Q

100. On August 13, 2018, the Individual Defendants caused the Company to file its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018 with the SEC (the "August 2018 10-Q"). The August 2018 10-Q was signed by Defendant Palmin, and contained SOX certifications signed by Defendants Schelling and Palmin attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

101. The August 2018 10-Q stated the following regarding the Company's internal controls:

> We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the SEC under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the SEC's rules and forms, and that information is accumulated and communicated to our management, including our principal executive officer and principal financial officer (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of June 30, 2018, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of June 30, 2018, our disclosure controls and procedures were effective.
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> There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that

> have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

October 29, 2018 Press Release

102. On October 29, 2018, the Individual Defendants caused Acer to issue a press release announcing the Company's submission of its NDA for EDSIVO to the FDA for the treatment of vEDS (the "October 2018 Press Release"). The October 2018 Press Release contained a statement by William Andrews ("Dr. Andrews"), M.D., FACP, the Chief Medical Officer of Acer. Dr. Andrews' statement touted EDSIVO's NDA as the culmination of the "extensive efforts" of, *inter alia*, Acer's employees and clinical sites, and Acer's continued work with the FDA as the FDA reviewed EDSIVO's NDA. Specifically, Dr. Andrews' statement in the October 2018 Press Release read:

> Our NDA submission represents the culmination of extensive efforts of our employees, investigators, clinical trial sites, contract research organizations, caregivers and patients . . . . We now look forward to continuing to work with the FDA as they review our NDA, with hopes to make EDSIVO™ available as quickly as possible in the U.S. We are grateful to the vEDS patient and advocacy community for their continued involvement, support and feedback as we work together to advance EDSIVO™, which has the potential to be a significant step forward in the care of patients with this devastating disease.

November 9, 2018 Form 10-Q

103. On November 9, 2018, the Individual Defendants caused the Company to file its Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018 with the SEC (the "November 2018 10-Q"). The November 201818 10-Q was

signed by defendant Palmin, and contained SOX certifications signed by defendants Schelling and Palmin attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

104. The November 2018 10-Q stated the following regarding the Company's internal controls:

> We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the SEC under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the SEC's rules and forms, and that information is accumulated and communicated to our management, including our principal executive officer and principal financial officer (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of September 30, 2018, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of September 30, 2018, our disclosure controls and procedures were effective.
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> * * *
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> There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

December 26, 2018 Press Release

105. On December 26, 2018, the Individual Defendants caused Acer to issue a press release announcing the FDA's acceptance of, and grant of priority review

for, the EDSIVO NDA (the "December 2018 Press Release"). The December 2018 Press Release boasted that the FDA's grant of priority review for EDSIVO's NDA indicated that EDSIVO "offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists."

106. The December 2018 Press Release also included a statement by Dr. Andrews, again touting EDSIVO's NDA, this time as the product of the Company's "hard work, passion and complete dedication[,]" which the Company would continue to exert alongside the FDA as EDSIVO's NDA was reviewed by the FDA. Specifically, Dr. Andrews' statement in the December 2018 Press Release read:

> The acceptance of our NDA for EDSIVO™ is an important step in our efforts to help patients with vEDS, who suffer with a devastating disease that currently has no approved treatment . . . . We have had the honor of learning about the significant challenges of living with vEDS directly from patients and their families. This has in large part driven the hard work, passion and complete dedication that our small team has given to this effort, and we will continue to do so as the FDA reviews our NDA for EDSIVO™. We are excited about the possibility of making EDSIVO™ available in the U.S. for patients in the near future.

107. The December 2018 Press Release also contained a statement by defendant Schelling, which touted Acer's "accelerat[ion]" of "pre-commercial activites" to launch EDSIVO in the United States. Specifically, defendant Schelling's statement in the December 2018 Press Release read:

> We continue to accelerate our pre-commercial activities supporting the potential U.S. launch of EDSIVO™ for the treatment of vEDS if it is approved by the FDA . . . . Additionally, we are working diligently on advancing and expanding our pipeline with the goal of bringing

> multiple products to patients with serious rare diseases over the next several years.

March 7, 2019 Form 10 K

108. On March 7, 2019, the Individual Defendants caused Acer to file an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the fiscal year ended December 31, 2018 (the "2018 10-K"). Under the 2018 10-K's "Rationale for EDSIVO™ Treatment in vEDS" section heading, the Individual Defendants again heavily relied upon the methodology and results of the Ong Trial.

109. Under the 2018 10-K's "Registration Plan" section heading for EDSIVO, the Individual Defendants touted the FDA's acceptance of EDSIVO's NDA for priority review, which purportedly meant that EDSIVO "offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists." Under the same section heading, the Individual Defendants touted "a manuscript for the Paris (AP-HP) vEDS patient registry data" that was "submitted for publication in a top-tier cardiology journal" and currently under peer review. According to the 2018 10-K, "[i]f published, [Defendants would] submit the manuscript to the FDA for review as part of our NDA and as supplemental data to the Ong trial."

110. Finally, the 2018 10-K touted the risk profile of the Company's drug candidates, stating, in relevant part:

> Our product candidates are believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation, and an accelerated path for development, which may include utilizing expedited programs (such as Priority Review) established by the FDA and/or using the regulatory pathway established under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FFDCA") that allows an applicant to rely at least in part on third-party data for approval, which may expedite the preparation, submission, and approval of a marketing application.

111. The 2018 10-K was signed by all of the Individual Defendants, and contained SOX certifications signed by defendants Schelling and Palmin attesting to the accuracy of the financial statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

April 12, 2019 Proxy Statement

112. On April 12, 2019, the Individual Defendants caused the Company to file the 2019 Proxy with the SEC. Defendants Schelling, Amello, Aselage, Birner, Dunn, Griffin, and Marengere each signed the 2019 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.

113. The 2019 Proxy Statement was false and misleading because, despite noting that the Company maintains procedures regarding "corporate governance and ethical conduct," such procedures, including the Code of Ethics, were not followed, as evidenced by the numerous false and misleading statements alleged herein, and

the Individual Defendants' failures to report violations of the Code of Ethics.

114. The 2019 Proxy Statement also failed to disclose, *inter alia*, that: (a) the Ong Trial was substantially biased and underpowered, and would be inadequate to support FDA approval of EDSIVO; (b) the FDA had not "agreed" that further clinical trials for EDSIVO were not needed for the approval of EDSIVO's NDA; (c) due to the foregoing, it was highly unlikely that EDSIVO's NDA would ultimately be approved; and (d) the Company failed to maintain an adequate system of internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

April 16, 2019 Press Release

115. On April 16, 2019, the Individual Defendants caused the Company to issue a press release touting the results of the Long-Term Observational Study in support of celiprolol, stating the following:

> The authors concluded that in this large, long-term cohort study, vEDS patients had a higher survival rate than expected relative to the known natural history of the disease and a lower annual occurrence of arterial complications, and that celiprolol use was potentially associated with these significant improvements in clinical outcomes.
>
> "The higher overall survival in patients treated with celiprolol in this long-term study in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the Ong, et al. study of celiprolol treatment in vEDS patients (2)," said Michael Frank, MD, clinical investigator from the Paris group and first author of the publication.

> "We are pleased to see this publication from the vEDS clinical investigator group in Paris which provides patients and physicians with a greater understanding of this chronic disease, including data suggesting a positive impact of celiprolol, which has a unique pharmacological profile," said William Andrews, MD, FACP, Chief Medical Officer of Acer.

116. As noted above, however, this selective quotation provided by the Individual Defendants lacked the proper framework. Indeed, the researchers of the Long-Term Observational Study noted that it was difficult to assess whether celiprolol actually increased the survivability of patients monitored in the study, as the study lacked a placebo-control, and therefore "other confounders" might have influenced the study's outcome.

May 14, 2019 Press Release

117. On May 14, 2019 the Individual Defendants caused the Company to issue another press release describing data that purportedly supported the efficacy of celiprolol, stating the following:

> Announced the publication of long-term data from a cohort of COL3A1-positive vascular Ehlers-Danlos syndrome (vEDS) patients in the Journal of the American College of Cardiology (JACC). The published data includes up to 17 years of safety data in this population, and the survival curve analysis shows that those patients not treated with celiprolol had a significantly worse outcome than celiprolol-treated patients. The authors also observed a relative decrease in hospitalization rates for acute arterial events during the time period in which the majority of patients were on celiprolol, suggesting a positive effect of celiprolol on the incidence and/or severity of new arterial events.

The Individual Defendants' Statements and Representations Were Materially False and Misleading

118. The Individual Defendants' public statements referenced above were materially false and misleading and failed to disclose material facts. Specifically, the Individual Defendants failed to disclose, *inter alia*, that: (a) the Ong Trial was substantially biased and underpowered, and would be inadequate to support FDA approval of EDSIVO; (b) the Long-Term Observational study into celiprolol was significantly limited, and would likewise be inadequate to support FDA approval of EDSIVO; (c) the FDA had not "agreed" that further clinical trials for EDSIVO were not needed for the approval of EDSIVO's NDA; (d) due to the foregoing, it was highly unlikely that EDSIVO's NDA would ultimately be approved; and (e) the Company failed to maintain an adequate system of internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

The Truth is Revealed

119. On June 25, 2019, Acer issued the June 2019 Press Release, disclosing that the FDA rejected the Company's NDA for EDSIVO. The June 2019 Press Release cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. Specifically, the June 2019 Press Release stated, in relevant part:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). ***The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS.*** Acer plans to request a meeting to discuss the FDA's response.
>
> "We remain committed to working closely with the FDA to fully understand its response," said Chris Schelling, CEO and Founder of Acer. "We expect to respond to the FDA in the third quarter of this year."

(Emphasis added.)

120. That same day, *Reuters* published an article titled "FDA declines to approve Acer Therapeutics' rare genetic disorder treatment" (the "*Reuters* Article"). In discussing the FDA's rejection of the Company's NDA, the *Reuters* Article noted, among other things, how ***"[t]he small group size"*** of the Ong Trial had ***"raised questions among experts about the adequacy of the trial results."*** (emphasis added).

121. Following this news, Acer's stock price fell $15.16 per share, or nearly ***79%***, to close at $4.12 per share on June 25, 2019.

122. On July 5, 2019, the Company issued a press release stating that due to the FDA's rejection of the NDA for EDSIVO, the Company would undergo a "corporate restructuring," stating the following:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced a corporate restructuring and update on its pipeline programs. Acer's headcount has been reduced from 48 to 19 employees and pre-commercial activities of EDSIVO™ (celiprolol) have been halted. The restructuring is expected to provide the resources needed for Acer to conduct its planned business operations through 2020. Acer intends to pursue discussions with the U.S. Food and Drug Administration (FDA) regarding its previously announced Complete Response Letter (CRL) for Acer's New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS), and to continue the development of Acer's additional pipeline programs, including ACER-001 and osanetant.
>
> "While we are disappointed by the CRL, we intend to continue our dialogue with the FDA to fully understand its response and work toward our goal of approval of EDSIVO™ for confirmed COL3A1+ vEDS patients, who currently have no approved treatment options," said Chris Schelling, CEO and Founder of Acer. "Nevertheless, in light of the CRL it was necessary to reduce our expenses, extend our cash runway, and focus our resources on a potential path forward for EDSIVO™ as well as continued development of our other pipeline opportunities."

123. On March 18, 2020, the Company issued a press release announcing that the FDA denied the Company's appeal of the complete response letter rejecting the EDSIVO NDA. The press release indicated that the Company was evaluating "possible next steps."

124. The Company's stock price has never recovered, and Acer stock currently trades for less than $3.25 per share.

125. As a result of the Individual Defendants' misconduct, the Securities Class Action was initiated against the Company and defendants Schelling and

Palmin in the U.S. District Court for the Southern District of New York, captioned *Skiadas v. Acer Therapeutics, Inc. et al*.

126. On June 16, 2020, U.S. District Judge Gregory H. Woods denied in substantial part the defendants' motion to dismiss the Securities Class Action, finding that it had been adequately alleged that a series of public statements issued by Acer, defendant Schelling, the Company's President and CEO, and defendant Palmin, the Company's CFO, which represented that the FDA had "agreed" that no additional clinical trials for EDSIVO were necessary for EDSIVO to receive FDA approval, were materially false and misleading. See Securities Class Action Order at 15–17.

127. Judge Woods further concluded that it had been plausibly alleged that the defendants to the Securities Class Action acted with scienter. In other words, Judge Woods found there was *indicia* that the defendants to the Securities Class Action participated in a scheme to defraud Acer investors during the Class Period.

DAMAGES TO THE COMPANY

128. As a direct and proximate result of the Individual Defendants' conduct, Acer has been seriously harmed and will continue to be seriously harmed. Such harm includes, but is not limited to:

a) Legal fees associated with the Securities Class Action filed against the Company, its President and CEO, and its CFO, and amounts paid

to outside lawyers, accountants, and investigators;

b) Any funds paid to settle the Securities Class Action; and

c) Costs incurred from compensation and benefits paid to the Individual Defendants who have breached their fiduciary duties.

129. In addition, as a direct and proximate result of the Individual Defendants' conduct, Acer has also suffered and will continue to suffer a loss of reputation and goodwill with its business partners, regulators, and stockholders.

130. For at least the foreseeable future, Acer will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Acer's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE ALLEGATIONS

131. Plaintiff brings this action derivatively in the right and for the benefit of Acer to redress injuries suffered, and to be suffered, by Acer as a direct result of non-exculpable breaches of fiduciary duty by the Individual Defendants, unjust enrichment, waste of corporate assets, and violations of the Exchange Act.

132. Acer is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

133. Plaintiff will adequately and fairly represent the interests of Acer in

enforcing and prosecuting its rights.

134. Plaintiff has continuously been a stockholder of Acer at times relevant to the wrongdoing complained of and is a current Acer stockholder.

DEMAND FUTILITY ALLEGATIONS

135. Plaintiff incorporates by reference and re-alleges each and every allegation stated above as if fully set forth herein.

136. A pre-suit demand on the Board of Acer is futile and, therefore, excused. At the time of filing of this derivative action, the Board consists of the following five members: defendants Schelling, Amello, Aselage, Dunn, and Griffin (collectively, the "Directors"). Plaintiff only needs to allege demand futility as to at least three of the five Directors that were on the Board at the time this action was commenced.

137. Demand is excused as to all five of the Directors because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to make, and/or cause the Company to make, false and misleading statements and omissions of material facts, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

138. The Directors abandoned their fiduciary duties to the Company and its

stockholders. Indeed, in violation of their non-exculpable fiduciary duties of loyalty and good faith, the Directors either knowingly or recklessly participated in making and/or causing the Company to make the materially false and misleading statements alleged herein, in order to make the Company appear more profitable and attractive to investors. Moreover, the Directors failed to maintain an adequate system of oversight, accounting controls and procedures, disclosure controls, and other internal controls, which were necessary to prevent or promptly correct the improper statements made on the Company's behalf.

139. As a result of the foregoing, the Directors breached their non-exculpable fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and accordingly excused.

140. Demand on defendant Schelling is futile for additional reasons. Defendant Schelling is the Company's founder and has served as the Company's President and CEO since September 2017. Thus, as the Board itself admits in the Company's public filings, he is not an independent director. The Company provides Defendant Schelling with his principal professional occupation, and he receives lucrative compensation, including $550,000 in 2018, and $1,467,211 in 2019 for his services. Defendant Schelling was ultimately responsible for all of the false and misleading statements and omissions that were made, including those contained in the Company's SEC filings and press releases referenced herein. As the Company's

highest ranking officer and as a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, defendant Schelling is a named individual defendant in the Securities Class Action, and has had federal securities claims sustained against him in that case, rendering it impossible for him to impartially and disinterestedly consider a demand. For these reasons, defendant Schelling breached his fiduciary duties, faces a substantial likelihood of personal liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

141. Demand on defendant Amello is futile for additional reasons. Defendant Amello has served as a Company director since September 2017. He also serves as a member of the Company's Audit Committee, which bestowed increased responsibilities on him regarding oversight of the Company's public filings and regulatory compliance. Defendant Amello has received and continues to receive compensation for his role as a director as described above. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously

disregarded his duties to protect corporate assets. Furthermore, defendant Amello signed, and thus personally made the false and misleading statements in the Company's 2017 and 2018 10-Ks, which Judge Woods of the Southern District of New York concluded were sufficiently alleged to contain materially false and misleading statements and been issued as part of a scheme to defraud Acer investors. For these reasons, defendant Amello breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

142. Demand on defendant Aselage is futile for additional reasons. Defendant Aselage has served as the Company's Chairman of the Board since September 2017. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, defendant Aselage signed, and thus personally made the false and misleading statements in the Company's 2017 and 2018 10-Ks, which Judge Woods of the Southern District of New York concluded were sufficiently alleged to contain materially false and misleading statements and been issued as part of a scheme to defraud Acer investors. For these reasons, defendant Aselage breached his fiduciary duties, faces a substantial likelihood of liability, is

not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

143. Demand on defendant Dunn is futile for additional reasons. Defendant Dunn has served as a Company director since September 2017. He also serves as a member of the Audit Committee, which bestowed increased responsibilities on him regarding oversight of the Company's public filings and regulatory compliance. As a trusted Company director, he conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Furthermore, defendant Dunn signed, and thus personally made the false and misleading statements in the Company's 2017 and 2018 10-Ks, which Judge Woods of the Southern District of New York concluded were sufficiently alleged to contain materially false and misleading statements and been issued as part of a scheme to defraud Acer investors. For these reasons, defendant Dunn breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

144. Demand on defendant Griffin is futile for additional reasons. Defendant Griffin has served as a Company director since September 2017. She also serves as the Chair of the Company's Audit Committee, which bestowed increased

responsibilities on her regarding oversight of the Company's public filings and regulatory compliance. As a trusted Company director, she conducted little, if any, oversight of the scheme to cause the Company to make false and misleading statements, consciously disregarded her duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. Furthermore, defendant Griffin signed, and thus personally made the false and misleading statements in the Company's 2017 and 2018 10-Ks, which Judge Woods of the Southern District of New York concluded were sufficiently alleged to contain materially false and misleading statements and been issued as part of a scheme to defraud Acer investors. For these reasons, defendant Griffin breached her fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon her is futile and, therefore, excused.

145. Demand on the Board is futile for additional reasons. Defendants Amello, Dunn, and Griffin (the "Audit Committee Defendants") served on the Company's Audit Committee during the Relevant Period. Pursuant to the Company's Audit Committee Charter, the Audit Committee Defendants were responsible for overseeing, *inter alia*, the Company's financial reporting process, the integrity of the Company's financial statements, the Company's compliance with legal and regulatory requirements, and the Company's internal controls over

financial reporting. The Audit Committee Defendants failed to ensure the integrity of the Company's financial statements, as they are charged to do under the Audit Committee Charter, allowing the Company to file a series of materially false and misleading financial statements with the SEC and to fail to maintain internal controls. The Audit Committee was also charged with ensuring the Company's regulatory compliance and communicating with governmental entities (like the FDA). The Audit Committee Defendants failed in their responsibilities and thus, the Audit Committee Defendants demand is excused as to them.

146. The Directors each have longstanding business and personal relationships with each other and the Individual Defendants that raise reason to doubt their ability to act independently and in the best interests of the Company and the stockholders. For example, defendants Schelling and Aselage both served in a number of senior roles at BioMarin Pharmaceutical Inc. between 2006 and 2012, including as Executive Director of Strategic Marketing and as Executive Vice President and Chief Business Officer, respectively. These conflicts of interest precluded the Directors from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct.

147. In violation of the Code of Ethics, the Directors conducted little, if any, oversight of the Company's internal controls over public reporting and of the Company's engagement in the Individual Defendants' scheme to issue materially

false and misleading statements to the public, and facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and violations of the Exchange Act. In violation of the Code of Ethics, the Directors failed to comply with the law. Thus, the Directors face a substantial likelihood of liability and demand is futile.

148. Acer has been and will continue to be exposed to significant losses due to the wrongdoing complained of, yet the Directors have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Acer any part of the damages Acer suffered and will continue to suffer. Thus, any demand upon the Directors would be futile.

149. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Directors can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Thus, any demand upon the Directors would be futile.

150. The acts complained of herein constitute violations of fiduciary duties owed by Acer officers and directors, and these acts are incapable of ratification.

151. The Directors may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Acer. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue themselves or certain of the officers of Acer, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

152. If there is no directors' and officers' liability insurance, then the Directors will not cause Acer to sue the Individual Defendants named herein. If they did, they would face uninsured individual liability. Accordingly, demand is futile and excused.

153. For the reasons noted above, at least three of the Directors cannot consider a demand with disinterestedness and independence. Accordingly, a demand on the Board is futile and excused.

COUNT I

Against Individual Defendants for Violations of Section 14(a) of the Exchange Act

154. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

155. The Section 14(a) claims are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) claims do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these nonfraud claims.

156. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security)

registered pursuant to section 12 of this title [15 U.S.C. § 78l]."

157. Rule 14a-9, promulgated pursuant to Section 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9.

158. Under the direction and watch of the Directors, the 2018 and 2019 Proxy Statements (the "Proxy Statements") failed to disclose, *inter alia*, that: (a) the Ong Trial was substantially biased and underpowered, and would be inadequate to support FDA approval of EDSIVO; (b) the FDA had not "agreed" that further clinical trials for EDSIVO were not needed for the approval of EDSIVO's NDA; (c) due to the foregoing, it was highly unlikely that EDSIVO's NDA would ultimately be approved; and (d) the Company failed to maintain internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

159. The Individual Defendants also caused the Proxy Statements to be false and misleading with regard to executive compensation in that they purported to employ "pay-for-performance" elements, while failing to disclose that the Company's financial prospects were misrepresented as a result of false and

misleading statements, causing the Company's share price to be artificially inflated and allowing the Individual Defendants to wrongfully benefit from the fraud alleged herein.

160. Moreover, the Proxy Statements were false and misleading when they discussed the Company's adherence to specific governance policies and procedures, due to the Individual Defendants' failures to abide by them and their engagement in the scheme to issue false and misleading statements and omissions of material fact.

161. In the exercise of reasonable care, the Individual Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the Proxy Statements were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the Proxy Statements, including, but not limited to: (a) with respect to the 2018 Proxy Statement, approval of the reincorporation of the Company as a Delaware corporation, approval of the 2018 Stock Incentive Plan, and approval of amendments to the Company's Certificate of Incorporation pertaining to stockholder action at certain meetings, future amendments to the Company's Certificate of Incorporation and Bylaws, and the implementation of a forum selection clause, among other things; (b) with respect to the 2019 Proxy Statement, advisory approval of executive compensation and advisory approval of the frequency of future advisory votes on

executive compensation; and (c) with respect to both Proxy Statements, election of directors and ratification of an independent auditor.

162. The false and misleading elements of the Proxy Statements led to the approval of the 2018 Stock Incentive Plan and to the re-election of Defendants Schelling, Amello, Aselage, Birner, Dunn, Griffin, and Marengere to the Board, which allowed them to continue breaching their fiduciary duties to Acer.

163. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the Proxy Statements.

164. Plaintiff on behalf of Acer has no adequate remedy at law.

COUNT II

Against Defendants Schelling and Palmin For Contribution Under §§10(b) and 21D of The Exchange Act

24. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

25. This claim is brought derivatively on behalf of the Company for contribution and indemnification against defendants Schelling and Palmin, each of whom is a named individual defendant in the Securities Action.

26. Acer is named as a defendant in the Securities Class Action, which asserts claims under the federal securities laws for, among other things, violation of §10(b) of the Exchange Act. If Acer is ultimately found liable for violating the federal securities laws, the Company's liability will arise, in whole or in part,

from the intentional, knowing, or reckless acts or omissions of defendants Schelling and/or Palmin, as alleged herein. The Company is entitled to receive contribution from those Defendants in connection with the Securities Class Action against the Company.

27. As directors and/or officers of Acer, defendants Schelling and Palmin had the power and/or ability to, and did, directly or indirectly control or influence the Company's business operations and financial affairs, including the content of public statements about Acer, and had the power and/or ability directly or indirectly to control or influence the specific corporate statements and conduct that violated §10(b) of the Exchange Act and SEC Rule 10b-5 as alleged above.

28. Defendants Schelling and Palmer are also liable under §10(b) of the Exchange Act, 15 U.S.C. §78j(b), pursuant to which there is a private right of action for contribution, and §21D of the Exchange Act, 15 U.S.C. §78u-4, which governs the application of any private right of action for contribution asserted pursuant to the Exchange Act.

29. Accordingly, Acer is entitled to all appropriate contribution or indemnification from defendants Schelling and Palmin, who are responsible for exposing Acer to liability under the federal securities laws.

COUNT III

Against Individual Defendants for Breach of Fiduciary Duties

165. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

166. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Acer's business and affairs.

167. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

168. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Acer.

169. In breach of their fiduciary duties owed to Acer, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (a) the Ong Trial was substantially biased and underpowered, and would be inadequate to support FDA approval of EDSIVO; (b) the Long-Term Observational study into celiprolol was significantly limited, and would likewise be inadequate to support FDA approval of EDSIVO; (c) the FDA had not "agreed" that further clinical trials for EDSIVO were not needed for the approval of EDSIVO's

NDA; (d) due to the foregoing, it was highly unlikely that EDSIVO's NDA would ultimately be approved; and (e) the Company failed to maintain an adequate system of internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

170. The Individual Defendants failed to correct and/or caused the Company to fail to rectify any of the wrongs described herein or correct the false and misleading statements and omissions of material fact referenced herein, rendering them personally liable to the Company for breaching their fiduciary duties.

171. In further breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls.

172. The Individual Defendants had actual or constructive knowledge that the Company issued materially false and misleading statements, and they failed to correct the Company's public statements. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of the Company's securities.

173. The Individual Defendants had actual or constructive knowledge that

they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of the Company's securities. The Individual Defendants, in good faith, should have taken appropriate action to correct the schemes alleged herein and to prevent them from continuing to occur.

174. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

175. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Acer has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

176. Plaintiff on behalf of Acer has no adequate remedy at law.

COUNT IV

Against Individual Defendants for Unjust Enrichment

177. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

178. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Acer.

179. The Individual Defendants either benefitted financially from the improper conduct or received unjustly lucrative bonuses tied to the false and misleading statements, or received bonuses, stock options, or similar compensation from Acer that was tied to the performance or artificially inflated valuation of Acer, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

180. Plaintiff, as a stockholder and a representative of Acer, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits—including from insider sales, benefits, and other compensation, including any performance-based or valuation-based compensation—obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary duties.

181. Plaintiff on behalf of Acer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of Acer, demands judgment as follows:

A. Declaring that Plaintiff may maintain this action on behalf of Acer and that Plaintiff is an adequate representative of the Company;

B. Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Acer;

C. Determining and awarding to Acer the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest;

D. Directing Acer and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Acer and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

i. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into

the policies and guidelines of the Board;

ii. a provision to permit the stockholders of Acer to nominate at least three candidates for election to the Board; and

iii. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

E. Awarding Acer restitution from the Individual Defendants, and each of them;

F. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

G. Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury.

Dated: July 6, 2020

Respectfully submitted,

deLeeuw Law LLC

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